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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,816	08/25/2000	Michael R. Yeaman	066742-0026	6324

41552 7590 04/04/2008

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/648,816	YEAMAN ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-69,76 and 79* is/are rejected.

7)☒ Claim(s) *70-75, 77 and 78* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 67-79 are pending.

Applicants' response filed on January 7, 2008 is acknowledged. Therefore, claims 67-79 are examined.

Informalities

The disclosure is objected to because of the following informalities:

2. The margins on the left side of drawings in Figs. 1 and 17-25 are not enough.

Appropriate correction is required.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 67-69, 76 and 79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent 6,743,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69, 76 and 79 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence:

aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3, 10 or 13. This is obvious variation in view of claim 1 of the patent which discloses an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10, 13 or 14. Both sets of claims cite an antimicrobial peptide comprising the amino acid sequence of SEQ ID NO:3, 10 or 13. Thus, claims 67-69, 76 and 79 in present application and claim 1 in the patent are obvious variations of an antimicrobial peptide comprising amino acid sequence of SEQ ID NO:3, 10 or 13.

Response to Arguments

Applicants request that the rejection be held in abeyance until there is an indication of allowable subject matter at which time Applicants will file a Terminal Disclaimer if appropriate. (page 4 of the response).

Applicants' response has been considered. Since a terminal disclaimer is not filed, the rejection is maintained.

4. Claims 67-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U. S. Patent 7,067,621. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 67-69 in the instant application disclose an isolated antimicrobial peptide consisting of an amino acid sequence of 13-74 amino acids with a 7 amino acid core sequence: aa1-aa2-aa3-aa4-aa5-aa6-aa7, where amino acid residue at each position is defined, and synthetic analogs of the 7 amino acid core sequence that retain antimicrobial activity; and an antimicrobial peptide comprising SEQ ID NO:3. This is obvious variation in view of claims 1-8 of the patent which

disclose a context-activating peptide comprising the amino acid sequence of SEQ ID NO:1, 2, 3 or 4, which contains the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys, and the specification indicates SEQ ID NO:1, 2, 3, or 4 has less anti-microbial activity than the anti-microbial peptide, RP-1 (column 4, line 50-column 5, line 56). Both sets of claims cite an antimicrobial peptide comprising the core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys. Thus, claims 67-69 in present application and claims 1-8 in the patent are obvious variations of an antimicrobial peptide comprising the amino acid core sequence of Ala-Leu-Tyr-Lys-Lys-Phe-Lys.

Applicants did not respond to the rejection.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 67-68 are rejected under 35 U.S.C. 102(b) as anticipated by Darveau *et al.* (U. S. Patent 5,409,898, April 1995).

Darveau *et al.* disclose cationic oligopeptides include Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly and the like, wherein the amino acid residues can be d-amino acid (column 7, lines 46-49), which has α helical amphiphilic structure and antibacterial activity (column 12, lines 31-32 and 49-54). The d-amino acid analog of the peptide has the sequence of dAla-dLeu-dTyr-dLys-dLys-dLeu-dLeu-dLys-dLys-dLeu-dLeu-dLys-dSer-dAla-dLys-dLys-dLeu-Gly (column 8, lines 15-17), which contains the synthetic

analog of the 7 amino acid core sequence (Ala-Leu-Tyr-Lys-Lys-Leu-Phe or Ala-Leu-Tyr-Lys-Lys-Phe-Lys), and the synthetic analog retains antimicrobial activity (claims 67-68).

Response to Arguments

Applicants indicate d-amino acid substitutions of the amino acid residues of Darveau *et al.*, which are neither identical to nor analogs of the recited residues, cannot anticipate claims 67-68. Darveau *et al.* has Leu-Leu at positions corresponding to aa6 and aa7. Substituting dLeu-dLeu at aa6 and aa7 represents synthetic analogs of the residues recited by Darveau *et al.* but not of the distinct amino acid residues recited in claim 67. Claim 67 requires that (1) one of aa6 and aa7 is selected from the group consisting of phenylalanine, tryptophan and tyrosine, dLeu is not a synthetic analog of phenylalanine, tryptophan or tyrosine. Accordingly, removal of the rejection of claims 67 and 68 under 35 U.S.C. § 102(b), as allegedly anticipated by Darveau et al. respectfully is requested (pages 4-5 of the response).

Applicants' response has been fully considered. However, the arguments are not found persuasive because of the following reasons. Darveau *et al.* disclose a synthetic analog of the cationic oligopeptide of Ala-Leu-Tyr-Lys-Lys-Leu-Leu-Lys-Lys-Leu-Leu-Lys-Ser-Ala-Lys-Lys-Leu-Gly, in which the amino acid residues are substituted with d-amino acids (column 7, lines 46-49; column 8, lines 15-17), which are the synthetic analogs of amino acids in the core sequence of the claimed peptide. Furthermore, the specification of the instant application (e.g., the second and third paragraphs at page 42) indicates synthetic analogs may include amino acid residues substituted with d-amino acid residues. Claim 67 indicates "one of aa6 and aa7 is selected from the group consisting of phenylalanine, tryptophan and tyrosine, such that when aa6 is phenylalanine aa7 is selected from the group consisting of lysine, arginine and

histidine, when aa6 is tryptophan aa7 is lysine, and when aa7 is phenylalanine aa6 is leucine; and synthetic analogs of the amino acids in said 7 amino acid core that retain antimicrobial activity. Since the antimicrobial peptide of claim 67 can contain Ala-Leu-Tyr-Lys-Lys-Leu-Phe, where d-Leu can be considered as a synthetic analog of Leu or Phe, since both Leu and Phe are hydrophobic amino acid residues. Therefore, Darveau *et al.* anticipates the claimed peptide.

Claim Objections

6. Claims 70-75, 77 and 78 are objected to because the claims are dependent from a rejected claim.

Conclusion

7. Claims 67-69, 76 and 79 are rejected; and claims 70-75, 77 and 78 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
March 31, 2008